

1 April 2002

Subj: DOD PROCEDURES GOVERNING THE USE OF TIKOSYN

Encl: (1) Tikosyn Procedures for DoD Utilization of Pfizer's Contracted Pharmacy
(2) Tikosyn Procedures for Military Treatment Facilities (MTF)
(3) Points of Contact List
(4) Suggested Communication for DoD Facilities

1. Tikosyn (dofetilide) is indicated for the maintenance of sinus rhythm in patients with atrial fibrillation / atrial flutter greater than one-week duration already converted to normal sinus rhythm, and the conversion of atrial fibrillation / atrial flutter to normal sinus rhythm. Because Tikosyn can cause life-threatening ventricular arrhythmia it should be reserved for patients who are highly symptomatic. The potential benefit to a patient should be carefully weighed against the associated risk by using the complete prescribing information (www.Tikosyn.com). Because of these significant risks, the FDA requires that the initial administration and titration of Tikosyn be performed in an inpatient setting, and that Pfizer, the manufacturer of Tikosyn, limit the distribution of Tikosyn only to those providers and pharmacists who have undergone training governing Tikosyn's safe and appropriate use.

2. Pfizer created a closed distribution system to assure compliance with FDA directives. Pfizer will designate providers as eligible Tikosyn prescribers only after training has been completed. The list of approved providers is maintained at www.tikosynlist.com. ~~The CVS mail order pharmacy is the only commercial pharmacy dispensing Tikosyn. Since CVS is not affiliated with DoD's retail network, a mechanism permitting CVS to fill Tikosyn prescriptions for DoD beneficiaries has been established (enclosure 1). Any DoD physician (military, civilian, contract or TRICARE network) whose patient intends to utilize the CVS point of service must follow the approved procedure. No other process will assure an appropriate supply.~~ [Note: subsequent to completion of this document, the CVS Procure mail order pharmacy became part of the retail network in all TRICARE regions, thus enabling patients to pay the usual TRICARE copay instead of filing an out-of-network claim.]

3. DoD has also established a process for MTF pharmacies to procure and dispense Tikosyn locally (enclosure 2). The policy became effective on 1 April 2002. MTF pharmacies choosing to dispense Tikosyn are required to comply with all FDA requirements, including registration of the patient and verification of provider training. Pfizer's local representatives will coordinate the training of the affected MTF staff. Pfizer and DoD contacts are provided in enclosure 3.

4. Any facility administering and dispensing Tikosyn must have a pharmacist and the prescribing physician(s) trained by Pfizer. Different scenarios can occur depending on whether the physician is MTF-based or not, and if the patient chooses to have their outpatient Tikosyn dispensed by the MTF or CVS pharmacy. The likely scenarios are:

- A. The physician is not based at the MTF and the patient prefers to use the CVS mail order pharmacy (e.g. patient receiving care in the TRICARE network). Under this scenario the prescribing physician and the facility pharmacy must contact the local Pfizer representative directly to get training and the necessary forms. After training is finished, the completed forms should be faxed to the CVS mail order pharmacy. CVS will process the prescription, enrolling the patient and verifying physician and pharmacy training. Enough drug to initiate, titrate, and begin outpatient therapy will be mailed by CVS to the hospital pharmacy. Upon discharge the patient will receive ongoing medication directly from CVS. In this scenario there is no MTF involvement.
- B. The physician is MTF-based, but the patient wishes to utilize CVS for their ongoing therapy (e.g. a patient referred into the MTF for sub-specialty care, but lives geographically remote to the MTF). In this case the MTF physician and Pharmacist must complete the training. The pharmacist and/or physician are responsible for educating the affected ward staff (nurse, medic, corpsman, etc.). The physician must complete and fax the forms, as indicated in A. CVS will send the Tikosyn to the MTF pharmacy, who is responsible for inpatient and initial discharge dispensing. Additional refills are ordered directly from CVS by the patient. The MTF pharmacy has no further involvement.
- C. The physician is MTF-based and the patient plans to use the MTF outpatient pharmacy (e.g. MTF – Prime enrolled patient). The physician and pharmacist complete the training, as in B. The MTF pharmacy orders Tikosyn directly from Pfizer using the drop-shipment mechanism. In addition to ward staff education, inpatient dispensing, and discharge dispensing, the MTF pharmacy provides ongoing therapy using its regular refill process. The MTF is responsible for all aspects of Tikosyn procurement and dispensing. The key steps MTFs must follow for Tikosyn to be prescribed, initiated and titrated on site are summarized in enclosure 4.

Additional scenarios are also plausible. Patients may be in situations where their MTF offers no, or limited, inpatient services. Initiating therapy at a non-MTF inpatient facility and subsequently returning to the MTF pharmacy for outpatient Tikosyn may be a viable option. This, and other related scenarios, will require coordination among the MTF, the Managed Care Support Contractor and the Lead Agency. Regions are encouraged to explore alternatives that may enhance their ability to provide cost-effective Tikosyn therapy.

5. The primary DoD point of contact for Tikosyn issues is LCDR Ted Briski at 210-295-2771 or Ted.Briski@amedd.army.mil

Dan Remund
COL, MS, USA
Director, DoD Pharmacoeconomic Center

**Tikosyn® [dofetilide] Department of Defense Procurement Procedures
& Program Objectives**
Out-patient Distribution to DoD Beneficiaries via Single Source
Mail Order Facility

To minimize the risk of induced arrhythmia, patients initiated or re-initiated on dofetilide should be placed for a minimum of 3 days in a facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation. For detailed instructions regarding dose selection, see the DOSAGE AND ADMINISTRATION section of the package labeling.

TIKOSYN is available only to hospitals and prescribers who have received appropriate TIKOSYN dosing and treatment initiation education (see Dosing Administration Section of the package insert)

Department of Defense [DoD] Facility Responsibility:

The DoD physician(s) who will be prescribing Tikosyn will complete the Tikosyn Education Program provided by the appropriate Pfizer representative

DoD facilities will provide on-going training to those DoD health care professionals involved in the administration of Tikosyn and care of Tikosyn patients.

Pfizer Responsibility:

Pfizer will provide the Tikosyn Education program to DoD physicians who request such education. These may be provided through in-services, monograph materials, audiovisual materials, or web-based materials.

Pfizer will provide DoD physicians with all forms that must be completed to document the mandated education.

Pfizer or its agent will maintain an accurate record of all confirmed DoD prescribers in its database.

Mail Order Pharmacy [CVS ProCare] Responsibility:

The Mail Order Pharmacy [CVS ProCare], upon receipt of an enrollment form for a DoD beneficiary will verify their eligibility status by calling the contact number.

If CVS ProCare does not have a contract with the Tricare MCO the patient will pay for the drug and seek reimbursement via the internal DOD process. [Note: CVS ProCare is now part of the retail pharmacy network in all TRICARE regions, enabling patients to pay the usual TRICARE copay instead of being required to file an out-of-network claim.]

Enclosure (1)

After verification of eligibility status and prior to the dispensing of the drug by CVS, the Pharmacy Enrollment form, a copy of the original prescription, and the following information will be faxed to the PDTS customer service center at 210-221-8131 [complete contact information provided on “Contact List” attached] for clinical adjudication:

- Patient identifying number: Sponsor SSN, Dependent Suffix (DDS) and Family Sequence Number (FSN) combined with a date of birth, and sex

The PDTS will indicate on the form [within 2 hours of receipt] additional drugs the patient is currently prescribed (PDTS Customer Service Support Center telephone number is 866-ASK4PEC)

- If no contraindicated drugs are in the patient database, the CVS form will be initialed by the pharmacist on the bottom portion of the CVS Pharmacy Enrollment form and faxed back to CVS ProCare
- If the patient’s clinical profile indicates the patient is taking a current drug which is a Tikosyn contraindication, the PDTS pharmacist will contact the physician listed on the Enrollment form
 - The PDTS pharmacist will inform the CVS ProCare pharmacist of the outcome of the discussion with the physician a) physician is aware of clinical profile and wants to continue with therapy; b) physician is aware of clinical profile and decides not to proceed with therapy
 - The CVS ProCare Enrollment form will be faxed back to CVS ProCare with the above information indicated on the form and initialed by the PDTS pharmacist.

Upon above disposition, CVS ProCare will fill script & ship to patient or destroy prescription and inform the patient and physician.

CVS ProCare will track the enrollment forms faxed to the PDTS and notify the Contact Person if the form is not received within the established timeframe.

CVS ProCare will ship Tikosyn according to standard pharmacy practice and in accordance with the existing Tikosyn program SOPs.

**Tikosyn® [dofetilide] Department of Defense Procurement Procedures
& Program Objectives
Direct Distribution to DoD Military Treatment Facilities (MTF)**

To minimize the risk of induced arrhythmia, patients initiated or re-initiated on dofetilide should be placed for a minimum of 3 days in a facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation. For detailed instructions regarding dose selection, see the DOSAGE AND ADMINISTRATION section of the package labeling.

TIKOSYN is available only to hospitals and prescribers who have received appropriate TIKOSYN dosing and treatment initiation education (see Dosing and Administration Section).

Department of Defense [DoD] Facility Responsibility:

The DoD physician(s) who will be prescribing Tikosyn will complete the Tikosyn Education Program provided by the appropriate Pfizer representative

The DoD pharmacists who will be dispensing Tikosyn will complete the Tikosyn Education Program provided by the appropriate Pfizer representative.

DoD facilities will provide on-going training to those DoD health care professionals involved in the administration of Tikosyn and care of Tikosyn patients.

Before dispensing Tikosyn, the DoD pharmacist will verify that the prescriber has completed the Tikosyn Education Program and that the patient is not taking any drugs that may be contraindicated for use with Tikosyn.

- The prescriber's DEA or State License number will be checked against the central database, maintained by Pfizer or its agent, to ensure that the prescriber is a confirmed participant.
- This database information is available through www.tikosynlist.com or an IVR 1-800-788-7353.

Pfizer Responsibility:

Pfizer will provide the Tikosyn Education program to DoD physicians who request such education. These may be provided through in-services, monograph materials, audiovisual materials, or web-based materials.

Pfizer will provide the Tikosyn Education program to DoD pharmacists and other DoD health care professionals who request such education. These may be provided through in-services, monograph materials, audiovisual materials, or web-based materials.

Enclosure (2)

Pfizer will provide DoD physicians and DoD pharmacists with all forms that must be completed to document the mandated education.

Pfizer or its agent will maintain an accurate record of all confirmed DoD prescribers and DoD pharmacy facilities in its database.

Pfizer will receive purchase orders from DoD in-patient or outpatient facility via phone or fax. The DoD facility will provide wholesaler information

- Pfizer will verify confirmation status of facility pharmacies and ship in-patient and outpatient material requirements to DoD facility via Drop Ship process
- DoD facility will receive Packing List with their material with PO number
- Pfizer Drop Ship invoice reflecting shipping account standard information including PO number, and FSS with IFF pricing will be sent to the MTF contracted wholesaler
- Payment will be sent to Pfizer, Inc. from the wholesaler

Tikosyn Education/Distribution Program Pfizer/DOD Contact List

		TITLE	RESPONSIBILITY	CONTACT INFORMATION
Pfizer, Inc.				
CATHY SAWYER	CUSTOMER SERVICE REPRESENTATIVE		Primary contact at Memphis Pfizer for Tikosyn distribution	1-800-533-4535 x6127 Cathy.sawyer@pfizer.com
DEBBIE SZYMCZAK	CUSTOMER SERVICE REPRESENTATIVE		Back up contact at Memphis Pfizer for Tikosyn distribution	1-800-533-4535 x6135 debbie.szymczak@pfizer.com
LARRY ICHNIOWSKI	USP CS MANAGER, CUSTOMER SERVICE		Manager for Customer Service, Memphis Pfizer	1-901-380-6133 larry.ichniowski@pfizer.com
LORRAINE DONAGHER	MARKETING MANAGER, TIKOSYN TEAM, PFIZER HQ		Marketing Manager and Manager for Tikosyn Education/Distribution Program	1-212-733-5379 lorraine.donagher@pfizer.com
KAREN FIXLER	MARKETING MANAGER, TIKOSYN TEAM, PFIZER HQ		Marketing Manager	1-212-733-6304 karen.fixler@pfizer.com
ARLENE RIVERA	ADMINISTRATOR ASSISTANT		AA for the Tikosyn Team at HQ	1-212-733-3565 Arlene.rivera@pfizer.com
PDTS				
CRYSTAL LITTLE			Primary contact: PDTS CSSC	1-866-ASK4PEC Fax Number: 210-221-8131 Mail Address for CSSC: 2421 Dickman Road BLDG 1001, Reid Hall Fort Sam Houston, Texas 78234
SONYA EDM			Secondary contact: PDTS CSSC	1-866-ASK4PEC
DOD				
LTC DON DE GROFF	DIRECTOR, PHARMACY BENEFITS OPERATIONS,		Coordinates pharmacy benefit operations within the DOD	210-295-2774 Donald.DeGroff@amedd.army.mil
LCDR TED BRISKI	DOD Pharmaceutical Procurement Coordinator		Coordinates pharmacy contracting issues within the DOD	210-295-2771 Ted.Briski@amedd.army.mil
CMD				
LYNDA ELBETTAH	PROCESS COORDINATOR-CMD		Liaison for the Tikosyn Education/Distribution	(212) 771-7359 lelbettah@cmdnewyork.com

Enclosure (3)

SUGGESTED COMMUNICATION FOR THE DOD FACILITIES

TIKOSYN® (dofetilide) is available only to hospitals and prescribers who have received appropriate TIKOSYN dosing and treatment initiation education.

- TIKOSYN® (dofetilide) will be available via direct shipments to DOD MTFs from Pfizer beginning April 1, 2002
- Prescribers and pharmacists interested in becoming educated should contact the Tikosyn Process Coordinator at 1-800-443-3180
- DOD hospitals or Federal Institutions that want to order Tikosyn should contact Pfizer Memphis Customer Services (Cathy Sawyer) at 1-800-533-4535 x6127. Hours of operation: 8:00 am – 4:30 pm CST
- After determining that an ordering hospital or pharmacy is a confirmed participant in the Tikosyn database, the Pfizer Customer Service / Memphis Representative will ship the requested quantity of Tikosyn, and a supply of additional materials described below:
 - For each 40 unit dose pack the Pfizer Customer Service / Memphis Representative will supply five [5] 14 capsule bottles of Tikosyn to be provided to the patient free of charge before discharge. Strength will be in accordance with final dose.
 - For each total in-patient order five [5] Patient Resource Kits to be provided to the patient free of charge before discharge, will be sent to the hospital unless they chose not to receive them.
- Prescribers should encourage patients who are receiving their benefits through the DOD to access their outpatient prescriptions at the MTF pharmacy. If they do not receive Tikosyn through their MTF pharmacy the physician will need to complete a CVS ProCare Pharmacy Enrollment form [attached] and fax the prescription to the number on the CVS ProCare form
- Call 877 TIKOSYN with additional questions or contact the Tikosyn Process Coordinator at 1-800-443-3180

Enclosure (4)